

Applicant: BRAZELL et al.  
Application No. 10/080,797

### **REMARKS**

Further to the Examiner's communication dated 9 November 2004, the claim identifiers have been amended. In an exercise of caution, the remainder of the text is repeated for the previously filed Amendment filed on 9 September 2004.

Additionally, the above amendments essentially are those suggested by the Examiner, except that the subject matter of the suggested claims were combined into independent claim 1. Accordingly, no new matter issue arises, and entry of the amendments is requested respectfully.

I. In item 4, claims 1-3, 7, 8, 27, 28, 30, 31 and 43-47 were rejected under 35 U.S.C. 102(b) over WO99/26480). The Examiner relies in part on claim 33 of the WO document.

The rejection is traversed for the following reasons.

There is precedent that stands for the proposition that a mere "shotgun" recitation of a number of species of a genus, does not always anticipate every species contained therein.

When a reference does not highlight a specific element from a genus of possible elements, anticipation does not exist as to that specific element. In re Kollman et al. (CCPA 1979) 595 F2d 48, 201 USPQ 193. Moreover, when the various species of a genus are typified by divergent properties, anticipation does not lie. In re Kalm (CCPA

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1967) 378 F2d 959, 154 USPQ 10. A generic formula of a vast number of species does not anticipate all species encompassed therein merely because they fall within the scope of the formula. In re Ruschig et al. (CCPA 1965) 343 F2d 965, 145 USPQ 274.

WO99/26480 ("the PCT") teaches at pages 11-14 possibly all conceivable means for administering a biological drug. An artisan would have a large list of delivery means from which to choose and to test to obtain the instantly claimed invention, and it is well known that different delivery means can have an impact on bioavailability. There is no highlighting and teaching of direct administration to the eye as claimed in the instant application.

The working examples teach only ex vivo transduction and engraftment of the transformed cells by standard subcutaneous, intravenous or intraperitoneal implantation. None of the working examples teaches direct administration of a vector to the eye. As noted in the paragraph bridging pages 13 and 14 of the PCT, transfer of the nucleic acid is the critical first step in gene therapy.

The PCT also is focused primarily on treating cancer, see for example, the sentence bridging pages 7 and 8, and the working examples.

Angiogenesis is a complicated process. Numerous different effector cells are involved and angiogenesis varies from tissue to tissue, and varies between normal tissues and diseased tissues. For example, Eberhard et al., Cancer Research 60, 1388-1393, 2000, teach that angiogenesis is heterogeneous, and little is known about how the process occurs in human tumors, page 1388, right column, first full paragraph.

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